Arguments/Remarks

The application has been amended. Independent claim 26 has been amended to include subject matter found at page 6, lines 2-5 of the application, as filed and in claim 30, now canceled. Moreover, independent claim 41 has been added, support for which can be found in pending claim 32, and in Example 4 of the application, as filed.

Claim Rejections Under 35 U.S.C. §103(a)

Chanda et al. in view of Chengalvala et al. and Morin et al.

The Examiner has rejected claims 26, 29, 30, 31, 33, 35 and 38-40 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chanda et al. (Virology, 1990, Vol. 175, 535-547) in view of Chengalvala et al. (Current Opinion in Biotechnology, October 1991, 2, 718-722) and Morin et al. (Proc. Natl. Acad. Sci. USA, July 1987, Vol. 84, 4626-4630). Claim 30 has been canceled, thereby obviating the rejection of this claim.

Claim 26 has been amended to recite the limitations of claim 30, now canceled. Applicants respectfully traverse the above rejection on the ground that Chanda et al., when either taken alone or in combination with Chengalvala et al. and Morin et al., fails to arrive at the present invention as specifically set forth in amended claim 26.

The Examiner's attention is drawn to amended independent claim 26, which now recites that the expression cassette further includes a coding sequence for the HIV-1 rev gene inserted in frame after the HIV-1 gp160 sequence and before the polyadenylation sequence.

In contrast to the present invention, Chanda et al. fails to disclose the use of a composition wherein the recombinant virus includes an expression cassette that contains both an HIV-1 env sequence (i.e., an HIV-1 gp160 sequence) and the rev gene. While Chanda et al. discloses use of a double recombinant, Ad7-rev-env, which contains both the rev and env genes, it was constructed by inserting the rev gene in the deleted E3 region under the control of the E3 promoter and the env gene in the terminal expression cassette under the control of the MLP promoter (Figure 1B, p. 539 of Chanda et al.). Therefore, Chanda et al. does not disclose use of a recombinant adenovirus that includes an expression cassette including both the rev gene and an env gene (i.e., an HIV-1 gp160 sequence), as specifically set forth in the claims. Moreover, the

arrangement in Chanda's recombinant is such that the rev gene is inserted before the env gene, which is different from the claimed invention.

There is also no suggestion in Chanda et al. to modify the double recombinant, Ad7-rev-env, by placing both the rev and env genes in the expression cassette, specifically in an arrangement where the rev gene is inserted after an env gene sequence, as presently claimed. Chanda et al. discloses that good levels of env production were produced when the rev and env genes are co-expressed from a single recombinant virus constructed such that rev is inserted in the E3 region and env is inserted in the terminal expression cassette (page 538, 2nd column). Given such disclosure, one of skill in the art would not be led to modify Chanda's Ad7-rev-env recombinant in the direction claimed. As the Examiner is aware, the proper test for patentability requires determining what the prior art would have led the skilled person to do, and not what they might try or find obvious to try.

As further evidence that one of skilled in the art would not have been led to modify Chanda's recombinant in the direction claimed, Applicants refer to the cited Vernon, et al. reference, which published after Chanda et al. As described in further detail below, Vernon et al. discloses that a recombinant containing the gag and pro coding regions was similar to the construction of recombinant adenoviruses containing the gene for the HIV-1 envelope protein described in Chanda et al.

The Chengalvala et al. and Morin et al. references fail to make up for the deficiencies of the primary reference. In particular, the Examiner appears to use Chengalvala et al. for its teaching with respect to the deletion of the E1 region and the use of a booster administration regimen; and Morin et al. for its disclosure concerning intranasal administration of an immunogenic composition.

In summary, independent claim 26 is patentably distinct over the primary reference, and the remaining references fail to fill its deficiencies. Therefore, claim 26 and the claims depending therefrom, including claims 29, 31, 33, 35 and 38-40, are patentable over the cited combination. In view of the amendments and remarks presented herewith, withdrawal of these rejections is respectfully requested.

Chanda et al. in view of Chengalvala et al. and Morin et al., as applied to claim 26, and in further view of Vernon et al.

The Examiner has rejected claims 26 and 32 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chanda et al. in view of Chengalvala et al. and Morin et al., as applied to claim 26, and in further view of Vernon et al. (Journal of General Virology, June 1991, Vol. 72, pp. 1243-1251).

Regarding the Vernon et al. reference, the Examiner states that Vernon et al. teaches an immunogenic composition comprising a recombinant adenovirus comprising an expression cassette containing a promoter, a nucleic acid sequence encoding the gag-pro region of HIV-1, and a polyadenylation signal sequence.

With respect to the rejection of claims 26 and 32, and in support of the patentability of new claim 41, Applicants respectfully draw the Examiner's attention to the first paragraph of the Methods section of Vernon et al. on p. 1244. Vernon et al. clearly discloses that the construction of recombinant adenoviruses containing the gag and pro coding regions was similar to the construction of recombinant adenoviruses containing the gene for the HIV-1 envelope protein described in Chanda et al. This is also evidenced by Fig. 1 of Vernon et al., which shows that the rev gene is inserted in the E3 region, whereas the gag/pro region is inserted in the expression cassette. Thus, Vernon et al. were clearly led by the disclosure in Chanda et al. to make a recombinant different from the one employed in the present invention.

Claim 32 is dependent upon claim 26. As set forth above, claim 26 is patentably distinct over the combination of Chanda et al., Chengalvala et al. and Morin et al. The Vernon et al. reference similarly fails to disclose or suggest administering a composition as specifically set forth in the claims wherein the recombinant virus includes an expression cassette that contains both (i) an HIV-1 env or gag/pro coding sequence and (ii) an HIV-1 rev gene, and with an arrangement such that the rev gene is inserted in frame after the env or gag/pro sequence. Therefore, withdrawal of the rejection of claim 26 and claim 32, which depends therefrom, is respectfully requested.

Chanda et al. in view of Chengalvala et al., as applied to claim 26, and in further view of Quantin et al.

The Examiner has rejected claims 26, 34 and 36 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chanda et al. in view of Chengalvala et al., as applied to claim 26, and in further view of Quantin et al. (Proc. Natl. Acad. Sci. USA, April 1992, Vol. 89, 2581-2584). The Examiner states that Quantin et al. teaches that an immunogenic composition comprising a recombinant adenovirus is able to direct expression of antigens in muscle cells. The Examiner asserts that this suggests intramuscular injections as a suitable form of delivery for the composition, and that it would be obvious to optimize the intramuscular dosage amount.

Claims 34 and 36 are dependent upon claim 26. As set forth above, claim 26 is patentably distinct over Chanda et al. in view of Chengalvala et al. The Quantin et al. reference fails to fill the deficiencies of Chanda et al. in view of Chengalvala et al. Therefore, withdrawal of the rejection of claims 26, and claims 34 and 36, which depend therefrom, is respectfully requested.

Chanda et al. in view of Chengalvala et al. and Morin et al., as applied to claim 26, and in further view of Haigwood et al.

The Examiner has rejected claims 26-27 and 37 under 35 U.S.C. §103(a) as allegedly being unpatentable over Chanda et al. in view of Chengalvala et al., as applied to claim 26, and in further view of Haigwood et al. (Journal of Virology, January 1992, Vol. 66, No. 1, 172-182). The Examiner states that Haigwood et al. teaches intramuscular administration of a recombinant envelope polypeptide to induce an immune response against HIV, as well as the use of booster administrations; and calculates the total dosage intramuscular amount of envelope polypeptide allegedly administered by Haigwood et al.

Claim 27 was previously canceled. Therefore, Applicants believe that the Examiner intended to reject pending claim 28 instead of claim 27. For this reason, Applicants will now address the rejection of claims 26, 28 and 37.

Claims 28 and 37 are dependent upon claim 26. As set forth above, claim 26 is patentably distinct over the combination of Chanda et al., Chengalvala et al. and Morin

et al. The Haigwood et al. reference similarly fails to disclose or suggest administering a composition as specifically set forth in the claims wherein the recombinant virus includes an expression cassette that contains both (i) an HIV-1 env or gag/pro coding sequence and (ii) an HIV-1 rev gene, and with an arrangement such that the rev gene is inserted in frame after the env or gag/pro sequence. Therefore, withdrawal of the rejection of claim 26, as well as claims 28 and 37, which depend therefrom, is respectfully requested.

Summary

Applicants have responded in full to the present Office Action. It is believed that all of the claims of the present invention are patentable over the cited references, either alone or in combination. Favorable action thereon is respectfully solicited.

Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned at the telephone number set forth below. If any additional fees are due in connection with this submission, the Commissioner is hereby authorized to charge them to Deposit Account No. 01-1425, or to credit any overpayment.

Respectfully submitted,

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